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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/634,038	08/08/2000	Gregory S. Keller	206066	5444
26211	7590	05/18/2006	EXAMINER	
FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			MATTHEWS, WILLIAM H	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/634,038

Applicant(s)

KELLER, GREGORY S.

Examiner

William H. Matthews (Howie)

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 6,7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. With regard to claims 16 and 17 and Naughton '152, Applicant contends '152 lacks disclosure or suggestion that anything is placed in a scar, Reinke's space, muscle of vocal cord, or lamina propria. Examiner disagrees because '152 describes in paragraph [0074] the composition is injected. From this alone, it is inherent the composition is implanted in the vocal cord. Furthermore paragraph [0014] states "These extracellular matrix preparations may be used to repair tissue defects by injection at the site of the defect". Furthermore, Applicant's disclosure at pages 14-17 of the specification describe the known procedures of treating vocal cord paralysis by injection of various materials into the vocal cords. Applicant further states Naughton lacks the step of "subadjacent the defect". Examiner interprets the defect in to be any part of the vocal cord in Naughton, so therefore injection of material into the vocal cord fulfills "subadjacent the defect".

2. With regard to claims 1-4,8,9,11 ('444 in view of '073), Applicant contends a lack of motivation between the references because '073 is related to collagen and the '444 relates to cells and teaches away from collagen, so therefore one of ordinary skill wouldn't look to the '073 reference. However, with respect to claims 1-4,8,9,11 the Examiner disagrees. Firstly, the rejected claims no longer include collagen. The '073 reference is only used to teach one of ordinary skill in the art of cosmetic or soft tissue augmentation surgery would know to apply similar methods for wrinkles, scars, **and** vocal cord defects. The references are related because cosmetic surgery and tissue augmentation (including repair of vocal cords) are be performed with similar techniques as shown by '073.

Art Unit: 3738

3. Regarding claims 1,2,5 ('001 or '025 in view of '138), Applicant contends (1) the '001 patent unclearly describe fat cells because of a typographical error, (2) an ordinary skilled artisan reading the background section of '025 would not look to '138, and that (3) the '001 and '025 references do not disclose where injection occurs. Note Applicant's arguments body contains incorrect reference to a '612 patent, which should read as the Vacanti '138 reference.

Examiner disagrees with (1) because the '001 patent states "Materials used for augmentation of tissues are, for instance, the patients own fat cell cartilage or other suitable materials." One of ordinary skill in the art, knowing "fat cell cartilage" does not exist, would interpret the intended teaching to read "...fat cell, cartilage, or other suitable materials." Regardless, Hubbard is also provided for the same primary teaching of utilizing fat cells to correct vocal cord defects. Regarding (2), the '138 reference is used to show it is well known in the art of tissue augmentation involving cell injections or implantation to culture the cells in order to provide enough cells to survive in vivo. The Examiner believes this to be sufficient motivation for one of ordinary in the art to look at other surgical techniques involving cell injection/implantation. Regarding (3), the references each disclose injection **into** the vocal cord, which is "vocal cord muscle", and comprises the defect such that injection into the defect meets the limitation "subadjacent".

4. Regarding claim 10, Applicant argues lack of motivation to combine the references to use autologous serum for culture medium. Examiner disagrees because the '444 reference clearly states at lines 47-58 of col. 4 that "Any tissue culture technique that is suitable for the propagation of dermal fibroblasts from biopsy specimens may be used to practice the invention." and "The medium can be any medium suited for the growth of primary fibroblast cultures."

Art Unit: 3738

Therefore it would have been clearly within the realm of one of ordinary skill in the art to look toward known tissue culturing techniques.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 16,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton US Pub. No. 2002/0038152 A1 in view of Applicant's admission or Hubbard USPN 5,922,025.

Naughton discloses in abstract and paragraphs 14-17,21-22,28-29,33-34,46-56,64,67, and 74 a method of corrective surgery for a vocal cord defect comprising the steps of retrieving cells from the patient's skin, culturing the cells in vitro with collagen to create extracellular matrix, separating the cells, and implanting the matrix by injection.

Naughton discloses "injection of the substance to repair vocal cord defects", but lacks the express written disclosure of injecting the substance into a vocal cord muscle. Each of Applicant's admission at pages 14-17 of the specification and Hubbard USPN 5,922,025 (lines 59 of col. 3 through line 3 of col. 4) teach vocal cord paralysis is treated by injection of material into the vocal cord muscle to impart more bulk.

Therefore it would have been obvious, if not inherent, to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Naughton '152 to include the step of

Art Unit: 3738

implanting the matrix directly into vocal cord muscle as taught by Applicant's specification or Hubbard in order to increase bulk of the vocal cord to treat vocal cord paralysis.

3. Claims 1-4,8,9,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boss Jr US PN 5,591,444 in view of Daniels et al. US PN 3,949,073.

Boss Jr discloses in line 22 of col. 3 through line 37 of col. 6 a method of corrective surgery comprising the steps of obtaining dermal fibroblast cells from the patient, culturing the cells in vitro, and implanting the cells by injection or engraftment. Boss Jr discloses example applications of the method such as depressed scars and wrinkles, but not expressly for vocal cord and furthermore lacks the express disclosure of including a phosphate buffered solution. Daniels et al. teaches a method of corrective surgery in lines 17 of col. 2 through line 59 of col. 5 for depressed scars and wrinkles as well as vocal cord defects. Furthermore, Daniels et al. discloses a rinsing step utilizing a phosphate buffered saline solution to rinse cells.

Therefore it would have been obvious to one of ordinary skill in the art to modify the method disclosed by Boss Jr by utilizing a phosphate buffered solution to rinse the cells and apply the method to tissue of the vocal cord to correct vocal cord defects as taught by Daniels et al. in order to treat a vocal cord.

4. Claims 1,2,5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agerup US PN 5,633,001 or Hubbard US PN 5,922,025 in view of Vacanti US PN 5,041,138.

Each of Agerup (lines 8-28 of col. 1) and Hubbard (line 52 of col. 3 through line 3 of col. 4) disclose a method of repairing a vocal cord defect by autologous adipose cell injections.

Art Unit: 3738

Agerup and Hubbard both lack the express written disclosure of culturing adipose cells in vitro before injection. Vacanti et al. teaches in abstract culturing cells in vitro before implantation in order to ensure adequate cell volume and density for the cells to survive in vivo.

Therefore it would have been obvious to one of ordinary skill in the art to modify the method disclosed by Agerup or Hubbard by culturing the cells in vitro before implantation as taught by Vacanti et al. in order to ensure adequate cell volume and density for the cells to survive in vivo.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boss Jr US PN 5,591,444 in view of Daniels et al. US PN 3,949,073 as applied to claim 1 above, and in further view of Osbourne et al. US ub 2004/0156833.

The method disclosed by Boss Jr. as modified by Daniels et al. meets the limitations of claim 10 as described above, and discloses using bovine serum but lacks the express written disclosure of using the patient's serum for culture medium. Osbourne et al. teaches in paragraph [0009] that it is well known in the art to use a patient's own serum for culturing cells for implantation to ensure biocompatibility of the implanted cells.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Boss Jr, as modified by Daniels et al., to include culturing the cells in the patient's own serum before implantation to ensure biocompatibility of the implanted cells.

Allowable Subject Matter

6. Claims 6,7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



WHM

May 15, 2006